

February 22, 2000

CENTER FOR VETERINARY BIOLOGICS NOTICE 00-04

Subject: Collaborative Studies on Moisture and Formaldehyde

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

The Center for Veterinary Biologics (CVB) announces an opportunity for licensees and permittees to participate in two international collaborative studies. The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) Biologicals Quality Monitoring Working Group has identified: 1) an assay to be included in the proposed VICH Residual Formaldehyde Guideline (commonly referred to as European Pharmacopoeia Method B and/or the Ferric Chloride Method) and 2) an assay to be included in the proposed VICH Residual Moisture Guideline (commonly referred to as the Gravimetric Method). Participants are needed for collaborative studies designed to evaluate the performance characteristics of the proposed assays. The purpose of this Notice is to identify Veterinary Biologics Establishments that are willing to participate as collaborators.

The CVB, on behalf of the Working Group, will invite a limited number of government and industry laboratories (less than five each) in each of the three VICH regions (United States, European Union, and Japan) to participate by testing collaborative samples by their current assay and the proposed harmonized assays. The number of samples to be tested will be less than ten for each method. The CVB will collect and distribute the data to the Working Group members for analysis. As with any collaborative study, confidentiality is maintained. The studies are intended to evaluate the reproducibility characteristics of the proposed assays and to provide a data basis for future equivalency studies or guidelines.

The CVB will select up to five collaborators based on experience with both proposed methods. The collaborative studies are designed to evaluate the performance of the proposed methods; therefore, experienced collaborators are desired.

Contact Frank Ross, Toxicology and Chemistry Section, National Veterinary Services Laboratories (phone 515-663-7542, fax 515-663-7210), VICH Biologicals Quality Monitoring Working Group, Moisture and Formaldehyde Topic U.S. Government expert, if you wish to be considered as a participant in the study. Submit the following information for each method by March 1, 2000: extent of experience, typical type of

product(s) tested, and number of tests conducted each month. The CVB will not distribute the information, but will only use it as a basis for selection. The CVB will notify selected and nonselected firms by March 3, 2000.

/s/ Randall L. Levings

Randall L. Levings
Director
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